IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO:	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
Fitt v. Ethicon, Inc, et al. **Case No. 2:14-cv-11545**	

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Caldera, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the Prolift Mesh.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the Prolift Mesh played in causing injury to Ms. Fitt. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient. In this instance, deposition testimony was available, so I reviewed that as well.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence and pelvic organ prolapse, medical literature, the reports of other experts as specified in my reliance list and otherwise discussed herein, and a review of relevant medical records and deposition testimony pertaining to Ms. Fitt. All of my opinions are true and correct to the best of my knowledge. Further, all of the opinions that I offer in this report I hold to a reasonable degree of medical and scientific certainty. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, depositions, articles or other relevant information). I also reserve the right to form rebuttal opinions and to perform a physical examination on Ms. Fitt.

B. Summary of Materials Reviewed

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Melynda Fitt:

- Inova Fairfax Hospital
- Dr. Jeffrey Welgoss
- VCU records

- Williamsburg Gynecology
- Tidewater Physicians Multispecialty Group
- University of Utah
- UCLA Medical Center
- Bayfront Same Day Surgery Center
- Dr Shlomo Raz
- White Wilson Medical
- Emerald Coast Compounding
- Sacred Heard
- Dr. Kimberly Hood
- Dr. Connie Richardson
- Dr. Alexander Wilson
- Tara Conshaw
- Dr. Edward Zbella
- Dr. Dionysios Veronkis
- Niceville Urgent Care
- Donald Whitaker
- St. Johns' Merchy
- Neurography Institute
- Dr Nitin Bawa
- Walmart Pharmacy
- Deposition of Melynda Fitt
- Deposition of Dr. Jeffrey Welgoss

C. Summary of a Collection of Pertinent Medical Facts related to Melynda Fitt

The following is a list of some, but not necessarily all, of the pertinent medical facts and history pertaining to Ms. Fitt. This is not intended to be an absolute and exhaustive medical summary of her medical history and/or everything I considered, but rather, some of the most relevant highlighted medical facts and history of which I reviewed and considered in forming my opinions:

PSX

LTCS, BTL,

PMH Significant for:

Depression, Possible Rheumatic Arthritis, Hepatic Cysts, Probable Undifferentiated Connective Tissue Disorder, Acanthosis Nigrans, Widened Pubis Symphysis, Pelvic Phleboliths, Obesity, Gallstones, Possible Diabetes, Borderline increased ANA Levels and Autoimmune Response, Prolapse, Fibroids and Uterine Cysts, Dyspareunia.

12/12/2005

33 year old female with 1+ year history of pelvic organ prolapse. Activity and gravity exacerbated vaginal bulging and pressure. Some stress incontinence. Dyspareunia that is excruciating at times and she localizes as probably in the region of the mid vagina. Prolift repair discussed.

12/23/2005

Radiographs show slightly widened symphysis without overt diastasis. Sacroiliac joins are symmetric and patent. Unremarkable hips and lumbar spine and pelvis. A few pelvic phleboliths are seen.

1/4/2006

She has multiple complaints of pubic symphysis aching, cramping and aching in the suprapubic region as well as dyspareunia. She reports increased pain with deeper penetration.

3/24/2006

She had a PT for her pelvic pain and musculoskeletal dysfunction. She has 10 treatments with 90% decrease in the tension of the pelvic floor muscles, iliopsoas, abdominal wall and adductor muscles by end of treatment

4/6/2006

A&P repair with mesh (Prolift), SSLF with suprapubic catheter. No complications.

5/3/2006

She reports anterior pain by coccyx. She is doing well after her Prolift.

6/7/2006

Follow up 2 months post op Prolift. No complaints of urinary or colorectal dysfunction. Incisions are healing well. Not masses or visceral tenderness. No evidence of mesh exposure. She has some bilateral pelvic floor tenderness and spasm although less prominent than it had been preoperatively.

10/23/2006

She had a positive pregnancy test. RLQ pain complaints (sharp and crampy). States symptoms have started gradually and radiate to the back. Possible ovarian cyst. Vaginal bleeding and RLQ pain.

11/24/2006

She has pain in her coccyx area.

11/30/2006

Generally normal and overall unremarkable pelvic ultrasound.

2/28/2008

She was referred to Dr Peggy Norton as she moved to Utah.

9/19/2008

Noted to have polycystic ovaries ("reason for exam"). Pelvic ultrasound showed normal uterine size and endometrial stripe and thickness. Small amount of cul-de-sac fluid, nonspecific. Otherwise unremarkable study.

1/12/2009

Complains of significant cramping with menstrual cycles. Feeling of deep discomfort where the mesh was placed. She denies pain with intercourse, but is able to feel suture line where mesh was placed. Feeling of incomplete emptying and occasional urge incontinence, but no SUI. Vaginal exam shows no signs of [mesh] erosion. Inspection of vaginal walls 360 degrees appears normal. Normal vaginal discharge. Exam confirms palpable scar tissue involving the anterior [vaginal] wall.

8/27/2009

Borderline positive ANA test noted and a variety of symptoms. Noted that in July 2006, she began noticing hair loss and developed severe headaches. In December 2006, she began experiencing severe fatigue. In Fall 2007, she began having some cognitive function problems. She has diffuse arthralgia for a year or longer. Hives noted, as well as palpitations and intermittent sharp pains in the anterior chest.

5/10/2010

LTCS, BTL, Tubal reversal

7/06/2012

Exploratory laparotomy with microsurgical tubal anastomosis performed.

7/14/2012

Possible infection from surgical wound. Abdominal pain. Fever. Drainage from surgical wound.

8/30/2012

Rash on her arms and legs. Complains of moderate throbbing and sharp pain in the suprapubic region and also in her back and vaginal area for the last 3 years. Abdominal pain developed 3 years ago.

9/11/2012

Presents to Kimberly Hood with pain that has worsened over the years. Pain with intercourse, bleeding with intercourse, and "can feel the mesh." Incomplete emptying. Pain scale 3-4 in pelvic area. Vaginal exam revealed a ridge in the anterior vagina that the patient reports is tender to the touch. No erosion noted. Good support.

9/24/2012

She reports pain ever since her Prolift was placed. The pain is twisting, standing and sitting. The pain is sharp and burning like a hot poker. She has issues with her pelvic floor muscles. Her husband is often deployed overseas and she does not have coitus regularly. She had a tight band 4 cm inside posterior wall on left side. She had another tight muscle 7 cm inside posterior wall is another tight mesh band 7 to 8 cm anterior wall sulcus. She had mesh erosion and contraction. (Dr. Norton). Assessment: mesh erosion from Prolift mesh kit; mesh contraction from same; levator tension myalgia; some neuropathic pain; no significant recurrence of POP.

12/03/2012

She reports pelvic pain, bleeding, and pain after intercourse. Recurrent urinary tract infections, leaking urine, and occasional loss of stool. Vaginal exam reveals 5mm exposed mesh in anterior compartment. No palpable mesh in posterior compartment. Does have pain over right periformis. Assessment: complications due to genitourinary device, implant, and graft.

12/13/2012

Noted that recent cysto and imaging showed two pelvic masses (one uterine, one on the left side). No bladder abnormalities at cysto.

12/19/2012

Consult at UCLA (Raz). Exam reveals no keloid scarring at puncture sites of mesh. Mild POP (grade 1 cystocele). She has mesh exposure along the anterior wall. Tenderness along palpation of the arms of the anterior implant. Posteriorly, it feels as though the mesh is infiltrated in the wall, however, not exposed.

5/16/2013

She was admitted at UCLA for mesh removal surgery. She has dyspareunia, vaginal pain and vaginal wall erosion. She has severe urinary and defecatory dysfunction. She underwent a cystolysis with removal of perivesical mesh, dissection and excision of mesh from obturator

fossa, anterior wall reconstruction, excision of posterior wall vaginal mesh with posterior wall reconstruction. She had EBL 700 ml, requiring transfusion. This surgery was very extensive. She was discharged on 5/20/2013.

10/30/2013

She has chronic pelvic pain and uses Neurontin, but has multiple side effects.

1/7/2014

She had an abdominal Supracervical hysterectomy, abdominal Sacrocolpopexy (Xenform), removal of pannus, enterocele, A&P repair with perineorrhaphy. (Dr Veronikis).

9/19/2014

She was found to have liver cysts and cholestasis.

9/22/2014

She reports an RUQ pain, nausea and diarrhea for one week.

12/22/2014

She had a laparascopic cholecystectomy with intraoperative cholangiogram.

7/29/2016

She had a soft tissue MR Neurography of the pelvis. There is evidence of entrapment affecting pudendal nerve with distortion of the course of the nerve increased caliber and increased image insistently at the sacrospinous ligament. There is evidence of trauma to the sacrospinous ligament on the left. She had obturator internus muscle spasm. There is clinical evidence of irritation of pudendal nerve at Alcock's canal. This is consistent with bilateral pudendal nerve syndrome.

9/13/2017

She has vaginitis pain. She has failed numerous options. Stopped Lyrica and Cymbalta due to nightmares.

12/21/2018

She reports pelvic pain and was started on vaginal compounding cream. She was seen by psychiatry at Mass General. She may have trigger points.

Her current complaints: she has a deep chronic pain, dyspareunia with the need to use OTC pains medicines, inability to stand more than 20 minutes, she can't sit longer than hour without pain, she has UTI's every 3 months, she has right sciatic nerve pain and radiating through leg,

groin and pelvic floor if she is on her feet for more than 2 hours and painful pulling and tension across her back.

She feels that she has an auto-immune reaction. She was told by her endocrinologist that they were unable to diagnose her. She felt better when she was pregnant.

D. Methodology, Analysis, and Conclusion.

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

In Ms. Fitt's case, it is my opinion that the following is a summary of the complications that Ms. Fitt suffered as a result of complications from the Prolift device:

- Vaginal pain (including dyspareunia);
- Mesh contraction and mesh extrusion (also referred to interchangeably by her treating doctors as mesh erosion);
- Painful scarification of vaginal tissues; and
- Two subsequent surgeries to remove mesh and correct the above complications.

The above complications necessitated a revision surgery (Raz) and then a subsequent vaginal repair (Veronikis). Ms. Fitt's pain and complications are severe and ongoing in nature. In considering the cause of the vaginal pain, vaginal scarification, vaginal extrusion, and the need for revision and repair surgery suffered by Ms. Fitt, I considered vaginal mesh as a potential cause because it is well accepted that pelvic floor mesh is causally associated with erosion/extrusion as well as scarification and shrinkage leading to pain and vaginal bleeding. Known sources of mesh related pain include nerve entrapment, tissue banding, chronic infection, chronic inflammation, and osteitis or adductor muscle damage.

The Prolift Pelvic Floor Repair Kit mesh implant is made with polypropylene mesh, which is known to be causally associated with pelvic pain, scarring in the vagina and pelvic floor, dyspareunia or painful intercourse, chronic inflammation of tissue and surrounding organs, scar bands or scar plates in the vagina, vaginal shortening, erosion of the mesh into tissues or organs, nerve entrapment as a result of mesh scarring and fibrotic bridging, constipation or fecal incontinence, encapsulation of the mesh; and deformed, curled, shrunken, folded, wrinkled, degraded and fragmented mesh after removal. Published medical literature also reports on these types of complications. Others have reported that polypropylene may not be inert and is susceptible to degradation due to oxidation caused by an inflammatory response.

Meyer et al reports dyspareunia rates of 36% at a 5 year follow up from mesh surgery. On the other hand, Alperin et al reports a dyspareunia rate of 28.9%, which was similar to

preoperative rate. Porter et al reports a site-specific posterior repair tends to have a positive effect on dyspareunia 73% cured vs. 19% where it increased.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Similar opinions and information have been stated and discussed in the expert reports of Dr. Dionysios K. Veronikis, Dr. Uwe Klinge and Dr. Paul J. Michaels, and I rely, at least in part, on these reports in reaching the conclusions made herein. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and dyspareunia suffered by Melynda Fitt, her Prolift mesh could contribute to causing her pain vaginal scarring, and noted mesh contraction or "banding" that was observed upon examination. Her chronic dyspareunia, and pelvic pain were caused by what Dr. Rosenzweig refers to as a chronic inflammation from the mesh. The general expert reports of Dr. Dionysios K. Veronikis, Dr. Uwe Klinge and Dr. Paul J. Michaels further discuss the issues and complications that result from chronic inflammation caused by the mesh implants. Her treating physicians also agreed with this assessment and they chose to remove the mesh. Dr. Norton identified a mesh contraction and erosion on examination. She also had an anterior and posterior mesh band identified in 2012. As per Dr. Klinge's opinion there may be safer alternatives to Gynecare's polypropylene (i.e. laser cut technology (less fraying) or different materials (PVDF)). Ethicon's Prolift is designed to cause a greater than necessary inflammation and foreign body reaction as is occurring in Ms. Fitt. Michaels et al reports inflammation and foreign body reaction at the interface between the mesh and the patient's tissue. These cellular responses result in a subsequent restriction (banding) of the graft leading to significant complications of chronic pain as what is happening with Ms. Fitt.

Liang et al concluded in their study relative to sham and the two lower stiffness meshes, Gynemesh PS had the greatest negative impact on vaginal histomorphology and composition. Compared with sham, implantation with Gynemesh PS caused substantial thinning of the smooth muscle layer increased apoptosis particularly in the area of the mesh fibres decreased collagen and elastin content and increased total collagenase activity. Glycosaminoglycan, a marker of tissue injury, was highest with Gynemesh PS compared with sham and other meshes. Deterioration of the mechanical properties of the vagina was highest following implantation with the stiffest mesh, Gynemesh PS. Liang et al further explained in another study's conclusion that following implantation with the heavier, less porous, and stiffer mesh, Gynemesh PS, the

degradation of vaginal collagen and elastin exceeded synthesis, most likely as a result of increased activity of active matrix metalloproteinase (MMPs), resulting in a structurally compromised tissue. High stiffness mesh can result in stress shielding. This occurs when the stiffer material bears the majority of the load. The soft tissue (less stiff) now shielded from the load it normally experiences a maladaptive remodeling response characterized by degeneration and atrophy (loss of collagen, elastin and skeletal/smooth muscle). Complications of mesh increase with time.

The next step in my analysis was to rule out other potential causes of her vaginal pain, dyspareunia, mesh contraction, and need for mesh removal surgery and subsequent repair surgery. I did consider and ruled out other non-mesh potential causes, including, but not limited to:

- Pre-existing pelvic pain, pelvic floor musculature myalgia, and dyspareunia;
- Pelvic abnormalities such as cysyts as documented above;
- Widened Pubic Symphasis;
- Possible immuno/inflammatory disorders; and
- Surgical error / deviation from the IFU.

I considered her entire previous medical history including, but not limited to, the above-documented history and complaints. It is noteworthy that, in her deposition, Ms. Fitt testified that her dyspareunia and pain differed post-mesh than before. Also, there is copious documentation of palpable mesh banding which is an indication of mesh contraction. There is also notable pain reproduced at the side of the mesh, and ridges/scar tissue and erosion in the location of the mesh (anterior). There is no notable lack of estrogen or improper estroginzation for her age. Also, with regard to her increased ANA levels and immune response, it is noteworthy that these symptoms presented after placement of the Prolift mesh.

It is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that:

1. Melynda Fitt's treating physician who implanted the Prolift met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications. Finally, I believe that Mrs. Fitt was an appropriate candidate for the procedures at the time or her implants.

2. Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Fitt's vaginal pain and dyspareunia, and the need for two subsequent surgeries are caused by her Prolift Mesh Implant.

3. Her Prolift removal was extensive in nature. Due to the extensive nature of the Prolift removal and the degree of increased pain and disability seen and discussed in her mesh removal operation and thereafter, her pain is most likely permanent in nature and will never be fully resolved.

4. She was an appropriate candidate for the Prolift device, however she was also an appropriate candidate for non-mesh repair. Furthermore, she was a candidate for mesh repair wherein with the use of other safer alternatives including biologic products, PVDF products, and/or repair with the use of polypropylene mesh with a safer profile (lighter-weight, open pore, not using "arms").

I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22nd day of February, 2019.

William Porter, M.D.

APPENDIX 1

CURRICULUM VITAE

WILLIAM E. PORTER, M. D.

OFFICE ADDRESS:

Presbyterian Urogynecology
6324 Fairview Rd, Suite 390
Charlotte, NC 28210
Phone: (704)316-1120 Fax: (704)316-1121
Email: urogynman@aim.com

PAST EMPLOYMENT:

Ob/Gyn Specialists of the Palm Beaches
1515 North Flagler, Suite 700
West Palm Beach, FL 33401
July 2003 - June 2008

EDUCATION:

High School:
Birmingham Groves
Birmingham, Michigan
Degree date – June 1987

Undergraduate:
University of Michigan
Ann Arbor, Michigan
Bachelor of Science in Biology
Degree date – May 1991

Graduate/Medical School:
University of Health Sciences
School of Osteopathic Medicine
Kansas City, MO
August 1992 – July 1993

Wayne State University
School of Medicine
Detroit, Michigan
Doctor of Medicine
Degree date – June 6, 1996

Internship:
University of Cincinnati
College of Medicine
Cincinnati, Ohio
Obstetrics and Gynecology
June 1996 - June 1997

Residency:
University of Cincinnati
College of Medicine
Cincinnati, Ohio
Obstetrics and Gynecology
June 1997 - June 2000

Fellowship:

University of Tennessee, Center of Health Sciences
Department of Obstetrics and Gynecology
Memphis, Tennessee
Urogynecology and Reconstructive Pelvic Surgery
Accredited Fellowship by ABOG
Directors: Robert L. Summitt, Jr. M.D., Val Y. Vogt, M.D.
July 2000 - June 2003

Honors:

Auxiliary to American Osteopathic Association Scholarship Finalist, 1993
Wayne County Medical Society Scholarship, 1995
Young Investigator Award Recipient, Central Association of Obstetrics and Gynecology, 2002

BOARD CERTIFICATION:

American Board of Obstetrics and Gynecology 2005
American Board of Obstetrics and Gynecology, 2013, Female Pelvic Medicine and Reconstructive Surgery

MEDICAL LICENSURE:

Ohio	35-07-6095	April 1999
Tennessee,	M.D. 34019	April 2000
Arkansas	E-2659	August 2000
Michigan	4301080975	October 2002 - 2016
Florida	ME87260	February 2003 – Present
North Carolina	01871	November 2007 - Present

SOCIETY MEMBERSHIPS:

American College of Obstetricians and Gynecologists, Fellow 2005
American Urogynecologic Society, January 2002 – present
Central Association of Obstetrics and Gynecology 2001 – present
American Association of Laparoscopic Gynecologist 2010 - 2012

UNIVERSITY APPOINTMENTS:

Instructor & Fellow, Section of Urogynecology
Department of Obstetrics and Gynecology, University of Tennessee, Memphis
Memphis, Tennessee, July 2000 - June 2003.

Assistant Professor, Campbell University,
School of Medicine, Buies Creek, NC
May 2016 to present

HOSPITAL APPOINTMENTS:

1. Presbyterian Hospital Charlotte, NC
2. Presbyterian Hospital, Matthews, NC
3. Presbyterian Hospital, Huntersville, NC
4. Carolinas Medical center, Charlotte, NC

TEACHING EXPERIENCE:

Provide lectures to the Residents in the Department of Obstetrics and Gynecology, University of Tennessee, Memphis, July 2000 – 2003.

- “Evaluation of Urinary Incontinence”

- "Evaluation of Fecal Incontinence"
- "Overactive Bladder"
- "Conservative Therapy for Stress Incontinence"
- "Surgical Management of Stress Management"

Give monthly clerkship lecture to third year medical students. Department of Obstetrics and Gynecology, University of Tennessee, Memphis, July 2000 – 2003.

- "Urinary Incontinence"
- "Pelvic Inflammatory Disease"

Urogynecology Conferences. Facilitate weekly resident conference where current articles and research are discussed. Department of Obstetrics and Gynecology, University of Tennessee, Memphis, July 2000 - 2003.

Urogynecology Chapter Review/Research Conference, conducted weekly with clinical fellows and residents. Department of Obstetrics and Gynecology, University of Tennessee, Memphis, July 2000 - 2003.

Council in Resident Education in Obstetrics and Gynecology (CREOG) May 2002

- Assisted in writing urogynecology questions for annual national in-service exam for obstetric and gynecology residents.

PUBLICATIONS (Book Chapters and Ad Hoc Reviews)

1. Porter WE, Penney DC: Cyanide. In Webb AR, Shapiro MJ, Singer M, Suter PM (eds). Oxford Textbook of Critical Care. Oxford Publishing, Oxford, England. 647-649, 1999.

2. Porter WE, Karram MM: Pathophysiology, diagnosis and management of rectocele. In Cardoza L, Staskin D (eds). The Textbook of Female Urology and Urogynecology. Isis Media Ltd., Oxford, England. 2001, 615-625.

3. Porter WE, Summitt RL: Posterior Colporrhaphy. In Sciarra J (ed). Obstetrics and Gynecology. Lippincott and Williams, New York. 2003.

4. Porter WE, Summitt RL: The Pathophysiology, Diagnosis, and Management of Rectoceles. In GLOWM (Global Library of Women's Medicine), 2008, Revised 2011

PUBLICATIONS (Peer Reviewed Journals):

1. Porter WE, Penney DG. Nitroprusside, A Cyanide Containing Drug: Recognizing the Dangers. Providence Hospital Medical Bulletin, 1996; 9(1): 23-28.

2. Porter WE, Steele A, Kohli N, Walsh P, Karram MM, The Anatomic and Functional Outcome of Defect-Specific Rectocele Repair. Am J Obstet Gynecol Dec 1999; 181(6): 1353-8.

ACADEMIC PRESENTATIONS: NATIONAL AND INTERNATIONAL MEETINGS AND PUBLISHED IN ABSTRACT FORM

1. Porter WE, Steele A, Kohli N, Walsh P, Karram MM: The Anatomic and Functional Outcome of Defect-Specific Rectocele Repair. Society of Gynecologic Surgeons Meeting, San Diego, California, March 1999.

2. Porter WE, Steele A, Kohli N, Walsh P, Karram MM: The Anatomic and Functional Outcome of Defect-Specific Rectocele Repair. International Urogynecology Association, Denver, Colorado, August 1999.

3. Porter WE, Haynes K, Lipscomb GH, Summitt RL, JR.: Oophorectomy at the Time of Vaginal Hysterectomy: A Prospective Study. Society of Gynecologic Surgeons Meeting, Dallas, TX, March 2002.

4. Porter WE, Yang C, Vogt V, Summitt RL Jr.: Isometric Detrusor Contraction During a Voiding Study: Its Meaning and Clinical Implications. American Urogynecology Society Meeting, San Francisco, CA October 2002.

5. Porter WE, Lipscomb GH, Stovall T, Ling F, Summitt RL, Jr.: A Prospective Randomized Comparison of Scalpel vs. Electrosurgery for Abdominal Incisions in Gynecologic Surgery. Central Association of Obstetrics and Gynecology Meeting. Las Vegas, NV October 2002.

6. Porter WE, Horton TR, Vogt VY, Summitt RL Jr: Historical and Physical Factors Predictive of Successful Pessary Use: American College of Obstetrics and Gynecology, Annual Clinical Meeting, New Orleans, LA April 2003.

7. Porter WE, Horton TR, Vogt VY, Summitt RL Jr: Genital Prolapse Symptoms and Quality of Life Parameters Associated with Pessary Use: American College of Obstetrics and Gynecology, Annual Clinical Meeting, New Orleans, LA April 2003.

8 Porter WE, Addis A, Vogt VY, Summitt RL Jr: Intrinsic Sphincter Deficiency: Association with Historical, Physical and Urodynamic Findings: American College of Obstetrics and Gynecology, Annual Clinical Meeting, New Orleans, LA April 2003.

9. Porter WE Anatomic Success of Porcine submucosa in Vaginal Surgery American Urogynecology Society Meeting, Hollywood, FL October 2009.

RESEARCH:

Sponsor:	National Institute of Health Student Training Grant at Wayne State University
Title:	Head and neck squamous cell cancer and the relevance of tumor marker P54.
Date:	August- September 1995
Staff:	Porter WE, Crissman JD
Sponsor:	Eli Lilly and Company
Title:	Efficacy and Safety of Duloxetine Compared with Placebo in Subjects with Symptoms of Bladder Overactivity Due to Pure Detrusor Instability or Sensory Urgency (Protocol # F1J-MC-SBBL)
Date:	May 2001
Staff:	Summitt RL, Vogt VY, Porter WE
Sponsor:	Milex Inc.
Title:	Predictors of Successful Pessary Management
Date:	May 2001
Staff:	Porter WE, Summitt RL, Vogt VY
Sponsor:	Bayer Pharmaceutical
Title:	Prospective, Randomized, Double-Blind Multicenter, Comparative Trial to Evaluate The Efficacy and Safety of Ciprofloxacin Once Daily Extended Release 500 mg Tablets QD for 3 Days Versus Conventional Ciprofloxacin 250 mg Tablets BID for 3 days in the Treatment of Patients with Uncomplicated Urinary Tract (uUTI) Infections (Bayer Study #100398)
Date:	July 2001
Staff:	Summitt RL, Vogt VY, Porter WE
Sponsor:	University of California, San Diego,
Title:	Identifying Bladder-Origin Pelvic Pain/Interstitial Cystitis in Gynecologic Patients and Their Treatment with Pentosan Polysulfate vs. Placebo.
Date:	September 2002
Staff:	Vogt VY, Ling FL, Summitt RL, Porter WE

Sponsor:	Timm Medical Technologies, Inc.
Title:	Normal Values for Vaginal Cone Weights in Asymptomatic Women.
Date:	September 2002
Staff:	Herrin A, Vogt VY, Summitt RL, Porter WE.

Sponsor:	Wyeth
Title:	A Double Blind, Randomized, Placebo and Active Controlled Safety and Efficacy Study of Bazedoxifene/Conjugated Estrogens Combinations in Postmenopausal Women
Date:	November 2002
Staff:	Summitt RL, Vogt VY, Porter WE, Horton TR.

Sponsor:	Pharmacia
Title:	Assessment of the Efficacy of Tolterodine ER vs. Placebo for the Symptom of Urgency and the Improvement in Bladder Condition (DETAOD-0084-047)
Date:	December 2002
Staff:	Summitt RL, Vogt VY, Porter WE, Horton TR

Sponsor:	Eli Lilly and Company
Title:	Long Term Monitoring of Safety in Subjects Treated with Duloxetine for Bladder Overactivity (F1j-MC-SBBX)
Date:	December 2002
Staff:	Summitt RL, Vogt VY, Porter WE, Horton TR

Sponsor:	US Surgical
Title:	A Prospective Multicenter Clinical Study on a New Approach in Treating Stress and Mixed Urinary Incontinence and Vaginal Vault Prolapse.
Date:	April 2005

Sponsor:	GlaxoSmithKline
Title:	An Observational, Pilot Study to determine the prevalence of Genital Herpes Infection in individuals who present to healthcare professionals complaining of pre-defined genital signs/symptoms.
Date:	April 2005

Sponsor:	Odyssey
Title:	Sanctura Study to Evaluate Control of Urinary Symptoms Resulting From OAB.
Date:	May 2005

Sponsor:	Sanctura
Title:	A Double-Blind, Multicenter, International, Randomized, Placebo-Controlled Study of Safety and Efficacy of Trospium Chloride 60mg Modified Release Capsules Versus Placebo, Once Daily, for 12 Weeks Followed by a 9 – Month, Open-Label Treatment Phase in Patients with Overactive Bladder.
Date:	July 2005

Sponsor:	Tyco
Title:	IVS Tunnler, Long Term Success of Pelvic Floor Prolapse and Stress Incontinence.
Date:	July 2005

Sponsor:	Boston Scientific
Title:	Prefyx Sling. Long Term Observation Registry
Date:	January 2007

Sponsor:	Cook Biomedical
Title:	Objective and Subjective Outcomes of Porcine SIS Graft Augmentation In Vagina; Prolapse Surgery.
Date	AUGS Annual Meeting for 2009

Sponsor: Mpathy and Coloplast
Title: TOT data collection
Date: Fall 2011 to Spring 2012

Sponsor: Boston Scientific
Title: Obtryx II vs Solyx 510 K study
Date: April 2013

Sponsor: Boston Scientific
Title: Uphold Vaginal Mesh 510 K study
Date: April 2013

INVITED LECTURES:

1. University of Tennessee, Department of Obstetrics and Gynecology.
Hot Topics in Women's Health. Memphis, TN. November 2000.
   - "Evaluation of Incontinence - What to Do and Why"
   - "Laparoscopic and Other Treatments for Urinary Incontinence"

2. University of Tennessee, Department of Family Medicine.
Update for the Primary Care Physician. Memphis, TN. March 2001.
   - “Evaluation of Incontinence for Primary Care Physician”
   - “Case Presentations: The Incontinent Patient”

3. South Central Obstetrics and Gynecology Meeting, *Annual Clinical Meeting*, Memphis, TN April 2002.
   - "Suburethral Sling Procedure for Urinary Incontinence"

4. University of Tennessee, Department of Obstetrics and Gynecology.
Fifth Annual Update in Gynecology, Reproductive Endocrinology Infertility and Urogynecology Grand Cayman Island, BWI, February 2003.
   - "Fecal Incontinence"
   - “Overactive Bladder”
   - “Lower Urinary Tract Symptoms”
   - “Neurological Injuries in Gynecology and Case Studies”
   - “Mesh use in Gynecologic Surgery”

5. Florida Obstetrics and Gynecology Society, *Annual Clinical Meeting.* Palm Beach, FL August 2006.
   - “Update in Urinary Incontinence”

6. Presbyterian Hospital, Department of Obstetrics and Gynecology.
Grand Rounds. Charlotte, NC. Various dates.
   - "Evaluation of Incontinence - What to Do and Why"
   - "Laparoscopic and Other Treatments for Urinary Incontinence"
   - “Lower Urinary Tract Symptoms”
   - “Fecal Incontinence”
   - “Treatment Update for Overactive Bladder”

7. Presbyterian Hospital, Department of Community Outreach

You Can Laugh Without Leaking. Charlotte, NC. October 2011.

- "Evaluation of Incontinence - What to Do and Why"

APPENDIX 2

APPENDIX 2

A. PRIOR TESTIMONY.

In the preceding four years, I have testified either as a witness or by deposition in the following legal actions:

Linda Liszak vs. Mentor Deposition
Ruth Haynes vs. C.R. Bard
Susan Falcone vs. C.R. Bard
Antoinette Angelo vs. C.R. Bard
Violet Lee vs. C.R. Bard
Janet Hachmeister vs. C.R. Bard
Wendy Baxter vs. C.R. Bard
Barbara Branch vs. C.R. Branch
Ashley Bevan vs. C.R. Bard
Eva Cantu vs. C.R. Bard
Peggy Kerr vs. C.R. Bard
Glenn Raymond, MD vs. Josephine Muhammad
Winebarager vs. C.R. Bard
Wiles vs. C.R. Bard
Penny Brown vs. C.R. Bard
Vicki Walters vs. C.R. Bard
Egynaim vs. Boston Scientific
Joanne Castellano- Cruz vs. Boston Scientific
Kimberly Mubita vs. Boston Scientific
April Fischer vs. Boston Scientific
Catherine Starks vs. Boston Scientific
Diana Cooper vs. Boston Scientific
Donna Edenfield vs. Boston Scientific
Donna Griffin vs. Boston Scientific
Valerie Bethune vs. Boston Scientific
Patti Smith vs. Boston Scientific
Mistee Robbins vs. Boston Scientific
Frances Smith vs. Mentor
Jeanne Hatfield vs. Mentor
Julie Echeveriria vs. Mentor
Julie Ford vs. Mentor
Teresa Taylor vs. Mentor
Blanca Roman vs. Mentor
Bernette Shaw-Wakeman vs. Mentor
Darlene Benson vs. Mentor
Melanie Cole vs. Mentor
Susan Herndon vs. Mentor
Mary Joan Adams vs. Ethicon
Marie Smith vs. Ethicon
Dee McBrayer vs. Ethicon

Joyce Justus vs. Ethicon
Terri Sively vs. Ethicon
Barbara Loomis vs. Ethicon
Carreen Schroeder vs. Ethicon
Margaret Schomer vs. Ethicon
Jacqueline Aldrich vs. Ethicon
Teresa Ferguson vs. Ethicon
Jessie Bishop vs. Ethicon

B. COMPENSATION.

My compensation per hour for my review, preparation and testimony is:

- Deposition testimony: $600.00 per hour with a $5000.00 minimum per day. 3 cases per a day in considered a full day regardless of hours, plus expenses. (10 days cancellation policy.);

- Expedited Case Review: $1000 per hour (less than 3 weeks notice);

- Court testimony: $10,000 per day plus travel and expenses. Court testimony: $10,000 per day plus travel ($250/hr.) and expenses. (14 days cancellation policy.); and

- Medical review and consultation fees: $550.00 per hour.

C. LITERATURE.

In preparing and formulating my opinions in this case, in in addition to the material identified above, I relied upon the medical literature I have reviewed over the past 10 years. I have read extensively from the Obstetrics and Gynecology, American Journal of Ob Gyn and Female Pelvic Medical and Reconstructive Surgery. I have read dozens of articles on the use of mesh and I am currently involved in a clinical trial using transvaginal mesh. I have performed several studies on mid urethral slings in the past. I have been asked to look at specific causation of problems. The general safety and success of these products are outside the scope of this report. I have specifically referred the articles listed below because I have found them useful in identifying mesh complications, and the mechanisms thereof, as well as identifying etiologies in establishing a differential diagnosis:

- Barski, D. et al, *Systemic review of classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapsed repair*, Surg Techno Int. 2014, 24:217-24;
- Chinthakanan, O. et al., *Indication and surgical treatment of Midurethral sling complications:* A Multi-center study, Int Urogynecol J, (2014), 25(suppl 1): S1-S240;
- Cholhan, H.L., Hutchings, T.B, Rooney, K.E., *Dyspareunia associated with paraurethral banding in the transobturator sling*, Am J Obstetrics and Gynecology, 2010; 202; 481.e1-5;
- Duckett, J, Baranowski, Pain after suburethral *sling insertion for urinary stress incontinence, Int Urogynecol J (2013) 24:195-201;*
- *Petri, E, Ashok, K. Comparison* of late complications of retropubic and transobturator slings in stress urinary incontinence, Int J Urogynecology (2012) 23:321-325;
- Petri, E, Ashok, K. *Complications of synthetic slings used in female incontinence and applicability of the new IUGA-ICS classification*. Eur J Obstetrics and Gynecology and Reproductive Biology 165 (2012) 347-351;
- Shah et al., *Mesh complications in female pelvic floor repair surgery and their management: A systemic review*. Indian J. Urol. 2012 Apr; 28(2): 129-53.
- Velemir, L. et al., *Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study*. Ultrasound Obstet Gynecol 2010; 35: 474-480.
- Shapiro, A; Dramitinos, P.; Hacker, M. R.; Hanaway, K. J.; Elkadry, E. A; Rosenblatt, P. L. Oral Poster 9: *Short Term Results Of PINNACLE® Procedure Used To Treat Anterior/apical Prolapse In 43 Patients Female Pelvic Medicine & Reconstructive Surgery*: March/April 2010 - Volume 16 - Issue 2 - p S19
- L Holmberg, H Anderson, *for the HABITS steering and data monitoring committees HABITS (hormonal replacement therapy after breast cancer—is it Safe?), a randomised comparison: trial stopped* THE LANCET • Vol 363 • February 7, 2004 •
- Edmiston CE et al *Microbiology of Explanted Suture Segments from Infected and Noninfected Surgical Patients* J Clin Microbiol. Feb 2013; 51(2): 417–421.

- Jeffery S. et al, *High risk of complications with a single incision pelvic floor repair kit: results of a retrospective case series*. Int Urogynecol J 25:109-116 (2014).
- U. Klinge, B. Klosterhalfen, M. Muller, A. P. Ottinger and V. Schumpelick, *Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs* Eur J Surg 1998; 164: 965–969
- Dietz HP, Vancaillie P, Svehla M, Walsh W, Steensma AB, Vancaillie TG *Mechanical properties of urogynecologic implant materials.* Int Urogynecol J Pelvic Floor Dysfunct. 2003 Oct; 14(4): 239-43; discussion 243. Epub 2003 Aug 5.
- Moalli PA, Papas N, Menefee S, Albo M, Meyn L, Abramowitch SD. *Tensile properties of five commonly used mid-urethral slings relative to the TVT*. Int Urogynecol J Pelvic Floor Dysfunct. 2008 May;19(5):655-63. doi: 10.1007/s00192-007-0499-1. Epub 2008 Jan 9.
- Abbott S, Unger CA, Evans JM, et al. *Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study*. Am J Obstet Gynecol 2014; 210:163.e1-8.
- Gerard Agnew & Peter L. Dwyer & Anna Rosamilia & Yik Lim & Geoffrey Edwards & Joseph K. Lee *Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence* Int Urogynecol J (2014) 25:235–239
- Eric A. Hurtado & Rodney A. Appell *Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience* Int Urogynecol J (2009) 20:11–17
- Naama Marcus-Braun & Peter von *Theobald Mesh removal following transvaginal mesh placement: a case series of 104 operations* Int Urogynecol J (2010) 21:423–430
- Nicklaus Trent Rice, MD; Yan Hu, MS; James Chris Slaughter, Dr; and Renee Melva Ward, MD, *Pelvic Mesh Complications in Women Before and after the 2011 FDA Public Health Notification* (Female Pelvic Med Reconstr Surg 2013;19: 333Y338)
- Serels, S Douso, M: *Long Term Follow up of the Solyx Single Incision Sling in the treatment of Female Stress Urinary Incontinence.* Open Journal of Urology, 2014, 4, 13-17
- Christine E. Skala, Karin Renezeder, Stefan Albrich, Alexander Puhl, Rosa M. Laterza, Gert Naumann, Heinz Koelbl *Mesh complications following prolapse surgery: management and outcome* European Journal of Obstetrics & Gynecology and Reproductive Biology 159 (2011) 453–456
- Skala & K. Renezeder & S. Albrich & A. Puhl & R. M. Laterza & G. Naumann & H. Koelbl *The IUGA/ICS classification of complications of prosthesis and graft insertion A comparative experience in incontinence and prolapse surgery* Int Urogynecol J (2011) 22:1429–1435
- Kamil Svabík & Alois Martan & Jaromir Masata & Rachid El-Haddad & Petr Hubka & Marketa Pavlikova *Ultrasound appearances after mesh implantation—evidence of mesh contraction or folding?* Int Urogynecol J (2011) 22:529–533
- Christopher Yang, MD; Loren Jones, MD; William H. Kobak, MD; Ervin Kocjancic, MD, *Single-incision slings: a strength comparison of immediate and*

delayed extraction forces of five anchor types in a rabbit model. Poster Presentation

- Myrthe M. Tijdink & Mark E. Vierhout & John P. Heesakkers & Mariëlla I. J. Withagen, *Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh* Int Urogynecol J (2011) 22:1395–1404
- Gutman RE, Nosti PA, Sokol AI, Sokol ER, Peterson JL, Wang H, Iglesia CB. *Three-year outcomes of vaginal mesh for prolapse: a randomized controlled trial.* Obstet Gynecol. 2013 Oct; 122(4):770-7.
- Noblett KL, Shen B, Lane FL. *Lynx midurethral sling system: a 1-year prospective study on efficacy and safety*. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Sep; 19(9): 1217-21
- Urinary Incontinence Treatment Network (TOMUS) *Trial of Mid Urethral Slings: Design and Methodology.* The Journal of Applied Research. Vol 8, No 1, 2008.
- Kaelin-Gambirasio I, Jacob S, Boulvain M, Dubuisson JB, Dällenbach P. 4. *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.* BMC Womens Health. 2009 Sep 25;9:28. doi: 10.1186/1472-6874-9-28.
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- Tahseen S, Reid PC, Charan P. *Short-term complications of the trans-obturator foramen procedure for urinary stress incontinence* J Obstet Gynaecol. 2007 Jul;27(5):500-2.
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- Hegde A, Nogueiras GM, Aguilar V, et al. *Dynamic assessment of sling function on tranperineal ultrasound: Is it correlated with outcomes one year following surgery?* (abstract). Female Pelvic Med Reconstr Surg 2013; 19:S57.
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Literature 2

Laila Najjari, [1,*] Julia Hennemann, [1] Ruth Kirschner-Hermanns, [2] Nicolai Maass, [1] and Thomas Papathemelis [1]

Visualization of Polypropylene and Polyvinylidene Fluoride Slings in Perineal Ultrasound and Correlation with Clinical Outcome Biomed Res Int. 2014; 2014: 181035.

Sabadell J[1,2], Larrain F[1,3,4], Gracia-Perez-Bonfils A[1], Montero-Armengol A[1], Salicrú S[1], Gil-Moreno A[1], Poza JL[1].
Comparative study of polyvinylidene fluoride and polypropylene suburethral slings in the treatment of female stress urinary incontinence. J Obstet Gynaecol Res. 2016 Mar;42(3):291-6. doi: 10.1111/jog.12899. Epub 2015 Dec 8.

Megan O. Schimpf, MD, Husam Abed, MD, Tatiana Sanses, MD, Amanda B. White, MD, Lior Lowenstein, MD, MS, Renée M. Ward, MD, Vivian W. Sung, MD, MPH, Ethan M. Balk, MD, MPH, and Miles Murphy, MD, MSPH, for the Society of Gynecologic Surgeons Systematic Review Group Graft and Mesh Use in Transvaginal, Prolapse Repair Obstet Gynecol 2016;128:81–91)

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Alexis L. Nolfi, BS, Bryan N. Brown, PhD, Rui Liang, MD, Stacy L. Palcsey, BS, Michael J. Bonidie, MD, Steven D. Abramowitch, PhD, and Pamela A. Moalli, MD, PhD

Host response to synthetic mesh in women with mesh complications Am J Obstet Gynecol. 2016_ August ;215(2): 206.e1–206.e8.doi:_10.1016/j.ajog.2016.04008

D. Expert General Testimony

Rule 26 Expert Report of Dr. Daniel Elliott Rule 26

Rule 26 Expert Report of Dr. Bruce Rosenzweig

Rule 26 Expert Report of Dr. Uwe Klinge

Rule 26 Expert Report of Dr. Dionysios Veronikis

Rule 26 Expert Report of Dr. Paul J. Michaels